DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 19 2009

Re: DORIBAX
Docket No.: FDA-2008-E-0266

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,317,016, filed by Shionogi Seiyaku Kabushiki Kaisha, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for DORIBAX (doripenem monohydrate), the human drug product claimed by the patent.

The total length of the regulatory review period for DORIBAX (doripenem monohydrate) is 1,746 days. Of this time, 1,442 days occurred during the testing phase and 304 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: January 2, 2003.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 2, 2003.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: December 13, 2006.

   The applicant claims December 12, 2006, as the date the new drug application (NDA) for DORIBAX (NDA 22-106) was initially submitted. However, FDA records indicate that NDA 22-106 was submitted on December 13, 2006.

3. The date the application was approved: October 12, 2007.

   FDA has verified the applicant's claim that NDA 22-106 was approved on October 12, 2007.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Philip Johnson, Esq.
Johnson & Johnson
Attn: Thomas J. Dodd
One Johnson & Johnson Plaza
New Brunswick, NJ 08893